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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,755	09/26/2003	Charles L. Truwit	1276.001US3	1029

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EXAMINER
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TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/672,755		TRUWIT, CHARLES L.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Rene Towa		3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-27, 39 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 28-38 and 40-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-27, 39 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/26/03</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species: species I directed to an outer tube with a slidable inner tube or cannula (figs. 1A-3A); species II directed to an outer tube with a slidable inner tube or cannula comprising a closure flap (figs. 4A-4D); and, species III directed to an outer tube with a slidable inner tube further comprising a biasing element (figs. 3B-3D). The species are distinct because of the reasons outlined above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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During a telephone conversation with Steve Lundberg on May 17, 2006 a provisional election was made without traverse to prosecute the invention of species II, claims 14-27, 39 & 45-47. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-13, 28-38 and 40-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Specification***

2. The disclosure is objected to because of the following informalities:

The Applicant has not disclosed the current status of the related applications.

Appropriate correction is required.

### ***Claim Objections***

3. Claims 39 and 45-47 are objected to because of the following informalities:

In regards to claim 39, at line 6, insert --outer-- after "beyond the."

In regards to claim 45, at line 7, insert --that-- between "such" and "the distal."

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 14, 17-18 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US Patent No. 5,797,888).

In regards to claim 14, Yoon disclose(s) a probe deflection device 20 comprising:  
an outer tube 22 having a proximal end and a distal end, the outer tube 22 including a closure 24 having an exit hole 29 defining a travel path; and  
an inner tube 26 fitted to slide within the outer tube 22 such that as the inner tube 26 slides through the exit hole, the inner tube 26 follows the travel path (see figs. 1, 3, 6 & 7).

In regards to claim 16, Yoon disclose(s) a probe deflection device wherein the closure has an actuator arm (i.e. from probe 62) accessible at the proximal end of the outer tube (see figs. 6-7).

In regards to claim 17, Yoon disclose(s) a probe deflection device wherein the closure is capable of being closed as the inner tube 26 is inserted into the outer tube 22 (see column 4/lines 42-49).

In regards to claim 18, Yoon disclose(s) a probe deflection device wherein the closure is capable of being open as the inner tube 26 is withdrawn into the outer tube 22 (see figs. 1, 3, 6 & 7; column 4/lines 42-49).

In regards to claim 25, Yoon disclose(s) a probe deflection device wherein the outer tube 22 is rotatable about the inner tube 26 (see figs. 1, 3, 6 & 7).

In regards to claim 26, Yoon disclose(s) a probe deflection device further comprising: a probe 62 inserted in the inner tube 26 (see figs. 6-7).

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6. Claims 14-15, 19-21 and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Selmon et al. (US Patent No. 6,217,527).

In regards to claim 14, Selmon et al. disclose(s) a probe deflection device 100 comprising:

an outer tube 102 having a proximal end and a distal end, the outer tube 102 including a closure 110 having an exit hole 122 defining a travel path; and

an inner tube 114 fitted to slide within the outer tube 102 such that as the inner tube 114 slides through the exit hole 122, the inner tube 114 follows the travel path.

In regards to claim 15, Selmon et al. disclose(s) a probe deflection device wherein the exit hole 122 includes a centerline that creates an oblique angle with the longitudinal axis (see figs. 7-9; column 12/lines 39-42).

In regards to claim 19, Selmon et al. disclose(s) a probe deflection device wherein the inner tube 114 is flexible (see figs. 7-9).

In regards to claim 20, Selmon et al. disclose(s) a probe deflection device wherein the inner tube 114 is fabricated from a material having memory (see column 12/lines 55-57).

In regards to claim 21, Selmon et al. disclose(s) a probe deflection device further comprising a flexible stylet GW capable of being inserted into the inner tube 114, the flexible stylet having a blunt and polished tip (see figs. 7-9; column 6/lines 38-48).

In regards to claim 25, Selmon et al. disclose(s) a probe deflection device wherein the outer tube 102 is rotatable about the inner tube 114 (see figs. 7-9).

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In regards to claim 26, Selmon et al. disclose(s) a probe deflection device further comprising: a probe GW inserted in the inner tube 114 (see figs. 7-9).

7. Claims 14 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bel et al. (US Patent No. 4,427,014).

In regards to claim 14, Bel et al. disclose(s) a probe deflection device comprising:  
an outer tube 1 having a proximal end and a distal end, the outer tube including a closure 3 having an exit hole 4 defining a travel path; and

an inner tube 2 fitted to slide within the outer tube such that as the inner tube 2 slides through the exit hole 4, the inner tube 2 follows the travel path (see figs. 4 & 6).

In regards to claim 16, Bel et al. disclose(s) a probe deflection device wherein the closure has an actuator arm 3 accessible at the proximal end of the outer tube (see fig. 4).

In regards to claim 17, Bel et al. disclose(s) a probe deflection device wherein the closure is capable of being closed as the inner tube is inserted into the outer tube (see figs. 4 & 6; column 2/lines 44-55).

In regards to claim 18, Bel et al. disclose(s) a probe deflection device wherein the closure is capable of being open as the inner tube is withdrawn into the outer tube (see figs. 4 & 6; column 2/lines 44-55).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Yoon ('888) and Bel et al. ('014) in view of Werne (US Patent No. 5,782,764).

Anyone of Yoon and Bel et al. disclose(s) a probe deflection device, as described above, that teaches all the limitations of the claim except anyone of Yoon and Bel et al. does not expressly teach a stylet. However, Werne discloses a medical stylet as follows:

In regards to claim 21, Werne discloses a probe device comprising a flexible stylet capable of being inserted into the inner tube, the flexible stylet 42 having a blunt polished tip 40A (see figs. 2 & 8-10).

In regards to claim 22, Werne disclose(s) a probe device comprising a flexible stylet 42 including an imaging contrast media 46 (see figs. 2-3 & 8-10; column 9/lines 61-67; column 10/lines 18-28).

In regards to claim 23, Werne disclose(s) a probe device comprising a stylet 42 having a cavity holding the imaging contrast media 46 (see figs. 2-3 & 8-10; column 9/lines 61-67; column 10/lines 18-28).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of anyone of Yoon and Bel et al. with a stylet similar to that of Werne in order to locate the position of the tissue collection recess (see Werne, column 9/line 67 to column 10/line 6). Moreover, since Werne teaches the use of a solution with a high proton density for MR image tracking (see column 10/lines 20-24), it would have been obvious to one of ordinary skill



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in the art at the time Applicant's invention was made to provide a device similar to that of anyone of Yoon and Bel et al. as modified by Werne with a saline solution marker, which is high in protons, since such a modification would amount to a design choice.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Yoon ('888), Selmon et al. ('527) and Bel et al. ('014) in view of Sidall et al. (US Patent No. 4,741,326).

Anyone of Yoon, Selmon et al. and Bel et al. disclose(s) a probe deflection device, as described above, that teaches all the limitations of the claim except anyone of Yoon, Selmon et al. and Bel et al. does not teach a sheath. However, Sidall et al. disclose(s) a probe device comprising a retractable sheath 1 (see fig. 3; column 3/lines 3-11). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of anyone of Yoon, Selmon et al. and Bel et al. with a sheath similar to that of Sidall et al. in order to prevent contamination of said device (see Sidall et al., column 3/lines 3-11).

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Selmon et al. ('527) in view of Yoon ('888).

In regards to claim 39, Selmon et al. disclose(s) a method of positioning a probe in a target area that is off axis from an outer tube inserted in a biological subject, the method comprising:

inserting an inner tube 114 having a tip into the outer tube 102 having an outer surface and a closure 110 having an exit hole 122 such that the tip extends through the exit hole and beyond the outer surface of the outer tube;

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inserting a probe GW into the inner tube 114 such that the probe GW extends beyond the surface of the outer tube 102; and

removing the inner tube 114 without deflecting of the probe GW (see figs. 7-9; column 13/lines 38-49 & 52-58).

Selmon et al. teach all the limitations of the claim except Selmon et al. do not teach a closure that opens and closes. However, Yoon discloses a probe deflection device comprising a closure 24 capable of closing and opening (see figs. 1, 3 & 6-7; column 4/lines 42-49). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Selmon et al. with a valve similar to that of Yoon et al. in order to prevent fluid flow through the catheter when no instrument is inserted therethrough (see Yoon, column 6/lines 2-5).

12. Claims 45-47 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Selmon et al. ('527).

In regards to claim 45, Selmon et al. disclose(s) a method of orienting an outer tube of a probe deflection device in a biological subject, the method comprising:

inserting an outer tube 102 having a surface and an off axis exit hole 122 into the biological subject;

inserting a stylet GW having an imaging marker and a blunt tip into an inner tube 114 to obturate the off axis exit hole 122;

inserting the inner tube 114 having a distal end into the outer tube 102 such that the distal end does not extend beyond the surface of the outer tube 102;

identifying an error in orientation of the outer tube using the imaging marker; and

if the error exceeds a predetermined value, rotating the outer tube to correct the error (see figs. 7-9; column 5/lines 14-25; column 6/lines 38-48; column 10/lines 38-45; column 11/lines 6-12 & 19-25; column 12/lines 32-38; column 13/lines 38-49 & 52-58; column 15/lines 61-63).

In regards to claim 46, Selmon et al. disclose(s) a method wherein identifying an error in orientation of the outer tube comprises:

using imaging to identify the orientation of the outer tube 102 (see column 11/lines 6-12 & 19-25; column 12/lines 32-38).

In regards to claim 47, Selmon et al. disclose(s) a method wherein using imaging to identify the orientation of the outer tube comprises:

imaging the imaging marker (see column 11/lines 6-12 & 19-25; column 12/lines 32-38).

It is noted that although Selmon et al. do not expressly teach the "error" step; however, from Selmon et al.'s method, the step appears to be implicitly taught in the sense that Selmon et al. teaches every step of the method without mentioning a feedback step. As such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Selmon et al. with a method step involving ascertaining and correcting the orientation of the outer tube in order to provide feedback (i.e. controlled orientation of the outer tube) to the method since such a modification would amount to a design choice.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,752,970 to Yoon discloses a cannula with a distal end valve.

US Patent No. 5,993,424 to Lorenzo et al. discloses a guidewire having a distal tip that change its shape within a vessel.

US Patent No. 5,217,026 to Stoy et al. discloses guidewires with lubricious surfaces.

US Patent No. 4,650,459 to Sheldon discloses a convolutedly wound paper tampon tube.

US Patent No. 4,023,559 to Gaskell discloses a sampling catheter device.

US Patent No. 4,157,709 to Schuster et al. discloses a probe for obtaining cervical mucus.

US Patent No. 5,354,302 to Ko discloses a medical device for facilitating intra-tissue visual observation and manipulation.

US Patent No. 5,129,402 to Koll et al. discloses an apparatus for collecting and/or growing protected biological specimens.

US Patent No. 5,109,830 to Cho discloses an apparatus for navigation of body cavities.

US Patent No. 5,984,939 to Yoon discloses a multifunctional grasping instrument with cutting member and operating channel for use in endoscopic procedures.

US Patent No. 4,774,949 to Fogarty discloses a deflector guiding catheter.

US Patent No. 3,958,576 to Komiya discloses a surgical instrument for clipping any affected portion of a body cavity.

US Patent No. 5,281,214 to Wilkins et al. discloses a disposable surgical probe having fiber diverter.

US Patent No. 5,201,908 to Jones discloses a sheath for protecting endoscope from contamination.

US Patent No. 5,496,280 to Vandenbrock et al. discloses a trocar valve assembly.

US Patent No. 5,779,680 to Yoon discloses a retractable safety needle instrument.

US Patent No. 5,392,766 to Masterson et al. discloses a system for cleaning viewing scope lenses.

US Patent No. 4,827,931 to Longmore discloses a surgical catheter with suturing device.

US Patent No. 5,607,435 to Sachdeva et al. discloses an instrument for endoscopic-type procedures.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RTT

  
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